



Sheet 1 of 1

SUBSTITUTE FORM PTO-1449 (MODIFIED)  U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)  (37 C.F.R. § 1.98(b))	Attorney Docket No.	50150/064001
	Serial No.	10/668,792
	Applicant	Bernard E. Cabana et al.
	Filing Date	September 23, 2003
	Group	1614
	IDS Filed	May 25, 2005
	Customer No.	21559

## U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)

## U.S. PUBLISHED PATENT APPLICATION

Examiner's Initials	Publication Number	Publication Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
PS	20040176404	09/09/04		514	252.13	
PS	20040126414	07/01/04		514	224.5	

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)

## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

PS	"Rifalazil PathoGenesis Plans Phase II Studies," R&D Focus Drug News. June 9, 1997.

EXAMINER	P. Spivack	DATE CONSIDERED	3/18/06
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EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.



Sheet 1 of 3

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## U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
PS	4,983,602	01/08/91	Yamane et al.	514	229.5	
PS	5,547,683	08/20/96	Yano et al.	424	501	
PS	5,786,349	07/28/98	Yamashita et al.	514	183	
PS	5,981,522	11/09/99	Yamashita et al.	514	224.5	
PS	6,316,433	11/13/01	Rose et al.	514	183	
PS	6,486,161	11/26/02	Fujii et al.	514	252.13	
PS	6,566,354	05/20/03	Rose et al.	514	183	

## U.S. PUBLISHED PATENT APPLICATION

Examiner's Initials	Publication Number	Publication Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
PS	20030203903	10/30/03	Rose et al.	514	229.8	
PS	20040034021	02/19/04	Michaelis et al.	514	310	
PS	20040077533	04/22/04	Chalom B. Sayada	514	8	
PS	20040106590	06/03/04	Barry Eisenstein	514	183	

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Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)

## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

PS	Bermudez et al., "Activity of KRM 1648 Alone or in Combination with Ethambutol or Clarithromycin Against Mycobacterium Avium in Beige Mouse Model of Disseminated Infection," <i>Antimicrobial Agents and Chemotherapy</i> 38(8):1844 (1994).
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PS	Dietze et al., "Safety and Bactericidal Activity of Rifalazil in Patients with Pulmonary Tuberculosis," <i>Antimicrobial Agents and Chemotherapy</i> 45(7):1972 (2001).
PS	Dhople AM, "In Vivo Susceptibility of Mycobacterium Ulcerans to KRM-1648, A New Benzoxazinorifamycin, in Comparison with Rifampicin," <i>Arzneimittelforschung</i> 51(6):501 (2001).
PS	Emori et al., "Evaluation of in Vivo Therapeutic Efficacy of a New Benzoxazinorifamycin, KRM-1648, in SCID Mouse Model for Disseminated Mycobacterium Avium Complex Infection," <i>International Journal of Antimicrobial Agents</i> 10(1):59 (1998).
PS	Fujii et al., "In Vitro and In Vivo Antibacterial Activities of KRM-1648 and KRM-1657, New Rifamycin Derivatives," <i>Antimicrobial Agents and Chemotherapy</i> 38:1118, (1994).
PS	Gidoh et al., "Bactericidal Action at Low Doses of a New Rifamycin Derivative, 3'-hydroxy-5'-(4-isobutyl-1-piperazinyl) Benzoxazinorifamycin (KRM-1648) on Mycobacterium Lepae Inoculated into Footpads of Nude Mice," <i>Leprosy Review</i> 63(4):319 (1992).
PS	Heep et al., "Detection of Rifabutin Resistance and Association of rpoB Mutation S with Resistance to Four Rifamycin Derivatives in Helicobacter Pylori," <i>European Journal of Clinical Microbiology &amp; Infectious Diseases</i> 21:143 (2002).
PS	Hirata et al., "In Vitro and In Vivo Activities of the Benzoxazinorifamycin KRM-1648 Against Mycobacterium Tuberculosis," <i>Antimicrobial Agents and Chemotherapy</i> 39 (10):2295 (1995).
PS	Hosoe et al., "Identification and Antimicrobial Activity of Urinary Metabolites of a Rifamycin Derivative in Dog," <i>Xenobiotica</i> 26(3):321 (1996).
PS	Hosoe et al., "Pharmacokinetics of KRM-1648, a New Benzoxazinorifamycin, in Rats and Dogs," <i>Antimicrobial Agents and Chemotherapy</i> 40(12):2749 (1996).
PS	Ji et al., "How Effective is KRM-1648 in Treatment of Disseminated Mycobacterium Avium Complex Infections in Beige Mice?," <i>Antimicrobial Agents and Chemotherapy</i> 40(2):437 (1996).
PS	Kelly et al., "Low-Dose Aerosol Infection Model for Testing Drugs for Efficacy Against Mycobacterium Tuberculosis," <i>Antimicrobial Agents and Chemotherapy</i> 40(12):2809 (1996).
PS	Klemens et al., "Activity of KRM-1648 in Combination with Isoniazid Against Mycobacterium Tuberculosis in a Murine Model," <i>Antimicrobial Agents and Chemotherapy</i> 40(2):298 (1996).
PS	Lenaerts et al., "Evaluation of Rifalazil in a Combination Treatment Regimen as an Alternative to Isoniazid-Rifampin Therapy in a Mouse Tuberculosis Model," <i>Antimicrobial Agents and Chemotherapy</i> 44(11):3167 (2000).
PS	Mae et al., "Effect of a New Rifamycin Derivative, Rifalazil, on Liver Microsomal Enzyme Induction in Rat and Dog," <i>Xenobiotica</i> 28(8):759 (1998).
PS	Mae et al., "Isolation and Identification of Major Metabolites of Rifalazil in Mouse and Human," <i>Xenobiotica</i> 29:1073 (1999).

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PS	Roblin et al., "In Vitro Activities of Rifamycin Derivatives ABI-1648 (Rifazil, KRM-1648), ABI-1657, and ABI-1131 Against Chlamydia Trachomatis and Recent Clinical Isolates of Chlamydia Pneumoniae," <i>Antimicrobial Agents and Chemotherapy</i> 47:1135 (2003).			
	Saito et al., "Therapeutic Efficacy of Benzoxazinorifamycin, KRM-1648, Against Disseminated Mycobacterium Avium Infection Induced in Rabbits," <i>Abstracts of the General Meeting of the American Society for Microbiology</i> 93:174 (1993).			
PS	Sano et al., "Therapeutic Effects of Benzoxazinorifamycin KRM-1648 Administered Alone or in Combination with a Half-sized Secretory Leukocyte Protease Inhibitor or the Nonsteroidal Anti-inflammatory Drug Diclofenac Sodium against Mycobacterium Avium Complex Infection in Mice," <i>Antimicrobial Agents and Chemotherapy</i> 43(2):360 (1999).			
PS	Sato et al., "Antimicrobial Activities of Benzoxazinorifamycin KRM-1648, Clarithromycin and Levofloxacin Against Intracellular Mycobacterium Avium Complex Phagocytosed by Murine Peritoneal Macrophages," <i>Journal of Antimicrobial Chemotherapy</i> 41(1):77 (1998).			
PS	Shimizu et al., "Effects of the Chinese Traditional Medicine Mao-bushi-saishin-to on Therapeutic Efficacy of a New Benzoxazinorifamycin, KRM-1648, Against Mycobacterium Avium Infection in Mice," <i>Antimicrobial Agents and Chemotherapy</i> 43(3):514 (1999).			
PS	Shoen et al., "Evaluation of Rifalazil in Long-term Treatment Regimens for Tuberculosis in Mice," <i>Antimicrobial Agents and Chemotherapy</i> 44(6):1458 (2000).			
PS	Tomioka et al., "Effects of Benzoxazinorifamycin KRM-1648 on Cytokine Production at Sites of Mycobacterium Avium Complex Infection Induced in Mice," <i>Antimicrobial Agents and Chemotherapy</i> 41(2):357 (1997).			
PS	Tomioka et al., "In Vivo Antileprosy Activity of the Newly Synthesized Benzoxazinorifamycin, KRM-1648," <i>International Journal of Leprosy</i> 61:255-258 (1993).			
PS	Tomioka et al., "Therapeutic Efficacy of KRM-1648 in Combination with Other Antimicrobials Against M. Leprae Infection Induced in Nude Mice," <i>International Journal of Leprosy and Other Mycobacterial Diseases</i> 61:77A (1993).			
PS	Tomioka et al., "Intramacrophage Passage of Mycobacterium Tuberculosis and M. Avium Complex Alters the drug susceptibilities of the organisms as determined by intracellular Susceptibility Testing using Macrophages and Type II Alveolar Epithelial Cells," <i>Antimicrobial Agents and Chemotherapy</i> 46:519 (2002).			
PS	Wallis et al., "Inhibition of Isoniazid-induced Expression of Mycobacterium Tuberculosis Antigen 85 in Sputum: Potential Surrogate Marker in Tuberculosis Chemotherapy Trials," <i>Antimicrobial Agents and Chemotherapy</i> 45(4):1302 (2001).			
PS	Yamamoto et al., "In Vitro Bactericidal and In Vivo Therapeutic Activities of a New Rifamycin Derivative, KRM-1648, Against Mycobacterium Tuberculosis," <i>Antimicrobial Agents and Chemotherapy</i> 40(2):426 (1996).			
PS	Yamamoto et al., "Activity of KRM-1648 Alone or in Combination with Both Ethambutol and Kanamycin or Clarithromycin Against Mycobacterium Intracellular Infections in Beige Mice," <i>Antimicrobial Agents and Chemotherapy</i> 40(2):429 (1996).			
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